

**REMARKS**

Claims 33-86 are pending in this application. Claims 33-72 and 81-86 have been withdrawn from consideration. Applicant has amended claim 76 to delete “(w/w)” to promote consistency with claims 74-75. Applicant has also amended claim 79 to recite “one or more diadzein metabolites,” which finds support in original claim 79 and throughout the specification, including at page 14, line 28, to page 15, line 2. Applicant has also amended claim 80 to recite “at least one daidzein metabolite” to more expressly recite the claim, which finds support in original claim 79 and throughout the specification, including at page 14, line 28, to page 15, line 2. No new matter is added. Following entry of the present amendment, claims 73-80 are under examination.

**Rejection of Claims 73-80 For Obviousness-Type Double Patenting**

The Examiner rejects claims 73-80 under the doctrine of obviousness-type double patenting as allegedly being upatentable over claim 11 of U.S. Patent No. 5,830,887 (the ‘887 patent). The Examiner states, “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the patented claim encompasses the scope of the instant claims.” Office Action at page 2. Applicant respectfully traverses.

The M.P.E.P. states that “any analysis employed in an obvious-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination.” M.P.E.P. § 804 at page 800-21. A *prima facie* case of obviousness first requires that there must be some suggestion or motivation to modify the references. M.P.E.P. § 2143.01 at 2100-135. Second, there must be a reasonable expectation of success. M.P.E.P. § 2143.02 at 2100-138. Third, all claim limitations must be taught or suggested by the prior art. M.P.E.P. § 2143.03 at 2100-139. The Office Action lacks any reference to the three basic criteria to establish a *prima*

*facie* case of obviousness, just the statement above.

Claim 73 recites:

73. A composition for the treatment or prevention of menopausal symptoms in a post-menopausal woman, said composition comprising an effective amount of formononetin and biochanin A wherein the level of biochanin A is less than about 10% w/w of the isoflavone content, and wherein genistein, if present, is in the amount of less than about 5% w/w.

Claim 11 of the '887 Patent recites as follows:

11. A pharmaceutical preparation, in solid dosage unit form, the biologically active component of said preparation consisting essentially of any two or more concentrated, phytoestrogen-derived isoflavones selected from the group consisting of Genistein, Daidzein, Biochanin A, Formononetin or the natural glycosides of any of said phytoestrogens and said preparation including a pharmaceutically acceptable carrier.

The percentages of the isoflavones in the composition make claim 73 (and its dependent claims) non-obvious over the compositions of the '887 patent. First, there is no suggestion in the '887 patent of a "composition for the treatment or prevention of menopausal symptoms in a post-menopausal woman" with the particular proportions of formononetin, Biochanin A, and, if present, genistein, as recited in claim 73. Second, the Office Action includes no discussion of an expectation of success, let alone a reasonable expectation of success. Third, the '887 patent does not teach or suggest all of the claim limitations. Specifically, the '887 patent does not teach a method for treatment or prevention of menopausal symptoms "wherein the level of biochanin A is less than about 10% w/w of the isoflavone content, and wherein genistein, if present, is in the amount of less than about 5% w/w." Indeed, the '887 patent teaches that the ratio of genistein or biochanin A to daidzein or formononetin should be between 1:2 to 2:1. *See* '887 patent at Col. 5, lines 63-66 ("It is also preferred that the ratio of genistein and/or its methylated derivative biochanin A to daidzein and/or its methylated derivative formononetin is between 1:2 to 2:1."); *see also* '887 patent, Claim 5 ("A method according to claim 1, wherein said phyto-estrogen

consists essentially of a) genistein and b) daidzein component, wherein component a) optionally contains biochanin A, and component b) optionally contains formononetin, and the ratio of a):b) is about 1:2 to 2:1.”). Claims 74-80 are dependent from claim 73, so the argument set forth above with respect to claim 73 applies to these claims, as well.

Accordingly, the ‘887 patent neither teaches nor suggests a preparation for the treatment or prevention of menopausal symptoms in a post-menopausal woman with the particular proportions of formononetin, Biochanin A, and, if present, genistein. Applicant respectfully requests reconsideration and withdrawal of the rejection under the judicially created doctrine of obviousness-type double patenting.

#### **Rejection of Claim 80 under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejects claim 80 under 35 U.S.C. § 112, second paragraph, as allegedly “being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.” Office Action at page 2. The Examiner states further that, in view of claim 79, “diadzein” is indefinite in claim 80. *Id.* Finally, the Examiner suggests, “[s]hould not “metabolite” be inserted after “diadzein” in claim 80?” *Id.* Applicant thanks the Examiner for this suggestion.

To facilitate prosecution, Applicant has amended claim 80 to recite:

80. (Currently Amended) A composition according to claim 79, wherein ~~the~~ at least one daidzein metabolite is in the aglycone, glycoside, malonyl or acetyl form.

Thus, the claimed invention is more expressly recited, and Applicant respectfully requests reconsideration and withdrawal of this rejection.

**CONCLUSION**

In view of the foregoing remarks, Applicant respectfully requests withdrawal of these rejections and timely allowance of the pending claims. Should the Examiner have remaining questions or concerns regarding this application, Applicant requests that the Examiner contact the undersigned at 650-849-6611 to schedule an interview to discuss the application.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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